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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,522	02/05/2001	Maria Altamura	205 010	4796

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,522

Applicant(s)

ALTAMURA et al.

Examiner

Brenda Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 18, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1624

DETAILED ACTION

Claims 21-33 are pending in the application.

This action is in response to applicants' amendment dated September 18, 2002. Claims 2-15, 19 and 20 have been canceled and claims 21-33 are newly added.

Response to Arguments

Applicants' arguments filed September 18, 2002 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections labeled a), b), c), e), f), i), j), k) and l) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, first paragraph rejections labeled d), g) and h) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

d) The applicants' stated that the "applicants have carefully reviewed each of the matters raised by the Examiner in her §112, 1st paragraph, rejection and have sought to amend the specification so that it is written in full, clear, concise, and exact terms". The definition of R₈ and R₉ together with the N atom to which they are linked to form a piperazine possibly substituted **on** one of its nitrogen atoms by C₁₋₃ alkyl, C₁₋₃ acyl or methanesulfonyl was amended to R₈ and R₉ together with the N atom to which they are linked to form a piperazine possibly substituted **at** one of its nitrogen atoms by C₁₋₃ alkyl, C₁₋₃ acyl or methanesulfonyl. However,

Art Unit: 1624

there is only one nitrogen atom which may be substituted. The other nitrogen is already valence satisfied.

- g) The applicants' stated that the "applicants have carefully reviewed each of the matters raised by the Examiner in her §112, 1st paragraph, rejection and have sought to amend the specification so that it is written in full, clear, concise, and exact terms". The definition of R₉ on page 5, line 15 has been amended such that the moiety 4-tetridrothiopyranyl was amended to 4-tetra**iod**rothiopyranyl.

However, it is not known what is meant by "iodro" in the moiety. It is believed that the applicants intended 4-tetrahydrothiopyranyl.

- h) The applicants' stated that the "applicants have carefully reviewed each of the matters raised by the Examiner in her §112, 1st paragraph, rejection and have sought to amend the specification so that it is written in full, clear, concise, and exact terms". The definition of R₉ on page 5, line 16 has been amended such that the moiety 1-oxo-tetridrothiopyran-4-yl was amended to 1-oxotetra**iod**rothiopyran-4-yl. However, it is not known what is meant by "iodro" in the moiety. It is believed that the applicants intended 1-oxotetrahydrothiopyran-4-yl.

2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a)-d), f), h), i), k)-n), q), r), u)-x), z)-ad), ai), aj), am),

Art Unit: 1624

ao)-ar), av) and aw), of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled e), g), j), o), p), s), t), y), ae), af), ag), ah), ak), al), an), as), at) and au), of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- e) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the point of attachment for the moiety $(CH_2)_rAr_1$ in the definition of R_3 has not been amended. (Claim 21)

- g) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the point of attachment for the moiety $(CH_2)_gR_{10}$ in the definition of R_9 has not been amended. There is no indication of the point of attachment nor has g been amended to a subscript. (Claims 21, 31 and 32)

- j) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definition of R_8 and R_9 has not been amended to clarify how the N atom which R_8 and R_9 are attached can be further substituted. (Claims 21, 31 and 32)

- o) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

Art Unit: 1624

However, the definition of R_4 has not been amended. R_4 is..... **or** or R_4 is selected from the group consisting of **and** is suggested. (Claims 21, 31 and 32)

- p) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definition of R_{13} has not been amended. It is not known what is meant by one or more "ether". (Claims 21, 31 and 32)

- s) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definitions of R_1 and R_2 have not been amended. It is not known what is meant by "are the same or different" when there is only one moiety.

(Claim 22)

- t) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definition of Ar has not been amended. It is not known what is meant by "up to two residues with substituents". What residues? (Claim 22)

- y) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definition of R_2 in claim 23 has not been amended. (Claim 23)

Art Unit: 1624

- ae) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".
However, the species have not been amended where X_3 is $-NHCO-$. (Claims 25, 27, 29 and 31)
- af) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".
However, the xiii) species has not been amended. (Claim 25)
- ag) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".
However, the xiv) species has not been amended. (Claim 25)
- ah) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".
However, the xiii) and xiv) species have not been amended with respect to the unmatched parenthesis. (Claim 25)
- ak) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".
However, the point of attachment for the moiety $(CH_2)_gR_{10}$ in the definition of R_9 has not been amended. There is no indication of the point of attachment nor has g been amended to a subscript. (Claim 26)

Art Unit: 1624

- al) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the species have not been amended. (Claim 27)

- an) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definition of R_{12} has not been amended with respect to the moieties 4-aminosulfonyl-piperazine and 4-hydroxy-cyclohexan-1-yl-amino. (Claims 28 and 29)

- as) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the species labeled xliii) has not been amended. (Claim 29)

- at) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the definition of R_{13} has not been amended. (Claim 30)

- au) The applicants' stated that "it is respectfully submitted that claims 21-33, inclusive, serve to overcome any claim indefiniteness as pointed out by the Examiner".

However, the species labeled xlvii) has not been amended. (Claim 31)

Claims 21-23 and 25-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

Art Unit: 1624

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection, of the last office action, which is hereby **withdrawn**.

4. The applicant's amendments and arguments are sufficient to overcome the provisional obviousness-type double patenting rejection, of the last office action, which is hereby **withdrawn**.

In view of the amendment dated September 18, 2002, the following new grounds of rejection apply:

Specification

5. The disclosure is objected to because of the following informalities: the definitions of variables X_1 , X_2 , X_3 , X_4 , R_1 , R_2 , R_3 , R_4 , Ar_1 , etc. all contain subscripts while the structural formula doesn't. It is also noted that in some instances CH₂ contains a subscript while in others they don't.

Appropriate correction is required.

6. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

a) on page 30, line 31 is missing part of the text because of "AMENDED SHEET".

Art Unit: 1624

7. The amendment filed September 18, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to the definition of Ar₁ includes a list of moieties which are substituted on the aromatic group. Within the list of substituents is the moiety CN, for which there is no description within the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the moieties in the list of substituents for the aromatic groups of R₃ where the aromatic group may be substituted with a CN is not described in the specification for the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

Art Unit: 1624

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21-24, 26, 28, 30, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 21 is vague and indefinite in that it is not known what is meant by **general** formula (I). A formula is not general when all of the variables are defined.
Deletion of “general” is suggested.
- b) Claims 21, 32 and 33 are vague and indefinite in that it is not known what is meant by the variables X₁, X₂, X₃, X₄, R₄ and Ar₁ which are not defined within the claim.
- c) Claims 21-24, 26, 28, 30, 32 and 33 are vague and indefinite in that it is not known what is meant by the definition of the variables X₁, X₂, X₃, X₄, R₄ and Ar₁, since there are no variables X₁, X₂, X₃, X₄, R₄ and Ar₁ in formula (I).
- d) Claims 21, 32 and 33 are vague and indefinite in that the moieties in the definition of f and m are not stated as a Markush group. **f and m are..... or or f and m are** selected from the group consisting of and is suggested.
- e) Claims 21-24, 26, 28, 30, 32 and 33 are vague and indefinite in that it is not known what is meant by the definitions of R₁, R₂, R₃ and R₄, since there are no variables R₁, R₂, R₃ and R₄ in formula (I).

Art Unit: 1624

- f) Claim 21 is vague and indefinite in that the moieties in the list of substituents for the aromatic groups of R_3 are not stated as a Markush group. It is not known what is meant by the extra "and" in the definition, i.e. C_{1-3} alkyl **and** haloalkyl, C_{1-3} alkyloxy **and** amino-alkyloxy, halogens, OH, NH_2 , CN and NR_6R_7 .
- g) Claims 21-23, 32 and 33 are vague and indefinite in that the definition of R_4 includes a moiety which fails to indicate the point of attachment.
- h) Claim 21 is vague and indefinite in that the definition of R_9 are not stated as a Markush group. It is not known what is meant by the extra "and" in the definition, i.e. methanesulfonyl, tosyl, **and** tetrahydropyranyl, tetrahydrothiopyranyl optionally mono or di-substituted by oxygen on the S atom, piperidyl, optionally substituted on the N-atom by a C_{1-3} alkyl, C_{1-3} acyl, aminosulfonyl, or methanesulfonyl; **or** a group $(CH_2)_gR_{10}$.
- i) Claim 21 is vague and indefinite in that it is not known what is meant by " $R_{8 \text{ and } 9}$ " where "and" is in the subscript.
- j) Claims 21-23, 32 and 33 are vague and indefinite in that it is not known what is meant by an "amino-cyclohexane optionally substituted on a hydroxy group" in the definition of R_{12} . Substituted on what hydroxy group.
- k) Claim 22 is vague and indefinite in that the moieties in the list of substituents for the aromatic groups of Ar are not stated as a Markush group. It is not known

Art Unit: 1624

what is meant by the extra "and" in the definition, i.e. C₁₋₃ alkyl **and** haloalkyl, C₁₋₃ alkyloxy, C₂₋₄ amino alkyloxy, halogens, OH, NH₂, CN, and NR₆R₇.

- l) Claim 22 recites the limitation "haloalkyl" in the definition of the substituents on the aromatic group. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
November 25, 2002